K050445

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JUN 17 2005

510(k) Summary
AMS Collagen Dermal Matrix

510(k) Number _____

Date of Summary Preparation:
February 18, 2005

Submitter/Contact Person:
Elsa A. Linke
Regulatory Affairs Specialist
American Medical Systems
10700 Bren Rd. W
Minnetonka, MN 55343

Phone: (952) 930-6000
Fax: (952) 930-6496

Device Name and Classification:
Trade Name(s): AMS Collagen Dermal Matrix
AMS Apogee System with Pre-Connected Collagen Dermal Matrix
AMS Perigee System with Pre-Connected Collagen Dermal Matrix
AMS Bioarc SP and Bioarc TO with Pre-Connected Collagen Dermal Matrix

Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh
Product Code: FTM for AMS Collagen Dermal Matrix
FTM & FTL for Apogee, Perigee, Bioarc SP & Bioarc TO with Pre-Connected Collagen Dermal Matrix
Classification: Class II

Manufacturing Location:
American Medical Systems, Inc.
10700 Bren Rd. West
Minnetonka, MN 55343

Predicate Devices:
For AMS Collagen Dermal Matrix :
DermMatrix/InteXen – K021160
Surgisis Sling – K992159

For AMS Bioarc SP & Bioarc TO with Pre-Connected Collagen Dermal Matrix :
AMS Bioarc SP – K040538
AMS Bioarc TO – K041948

For AMS Perigee System with Pre-Connected Collagen Dermal Matrix :
AMS Perigee System – K040623

For AMS Apogee System with Pre-Connected Collagen Dermal Matrix :
AMS Apogee System – K040537

Indications for Use:
The AMS collagen dermal matrix is intended for use in the treatment of hernias where the connective tissue has ruptured or for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy. This includes but is

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not limited to the following procedures: pubourethral support including urethral slings, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, sacral colposuspension and reinforcement in the repair of Peyronie's disease. By providing pubourethral support, the AMS collagen dermal matrix may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

The Bioarc SP Sling Kit with Pre-connected Collagen Dermal Matrix and Bioarc TO Subfascial Hammock with Pre-connected Collagen Dermal Matrix are intended for the placement of a pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The AMS Perigee System with Pre-Connected Collagen Dermal Matrix is intended for the placement of graft material in the anterior vaginal wall via the obturator foramen for the treatment of anterior wall prolapse.

The AMS Apogee System with Pre-Connected Collagen Dermal Matrix is intended for use in vaginal vault suspension to treat pelvic organ prolapse.

Device Description:

The AMS collagen dermal matrix is decellularized porcine dermis that is lyophilized and terminally sterilized. The product is available in a range of sizes.

The Bioarc SP Sling Kit with Pre-connected Collagen Dermal Matrix and Bioarc TO Subfascial Hammock with Pre-connected Collagen Dermal Matrix consist of needles and connectors used to pass a polypropylene mesh preconnected to porcine dermis for use as a urethral sling.

The Perigee System with Pre-Connected Collagen Dermal Matrix consists of needles and connectors used to pass a polypropylene mesh preconnected to porcine dermis in support of the anterior vaginal wall.

The AMS Apogee System with Pre-Connected Collagen Dermal Matrix consists of needles and connectors used to pass a polypropylene mesh preconnected to porcine dermis in support of the vaginal vault.

Summary of Testing

The AMS collagen dermal matrix and all of the pre-connected devices have been tested in accordance with the requirements of FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh and has been shown to be equivalent to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2005

Ms. Elsa A. Linke
Regulatory Affairs Specialist
American Medical Systems Incorporated
10700 Bern Road West
Minnetonka, Minnesota 55343

Re: K050445
Trade/Device Name: AMS Collagen Dermal Matrix, AMS Apogee System with Pre-Connected AMS Collagen Dermal Matrix, AMS Perigee System with Pre-Connected AMS Collagen Dermal Matrix, AMS BioArc™ SP Sling Kit and BioArc To Subfascial Hammock with Pre-connected AMS Collagen Dermal Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: May 24, 2005
Received: May 25, 2005

Dear Ms. Linke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050445

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: AMS Collagen Dermal Matrix

Indications For Use:

The AMS collagen dermal matrix is intended for use in the treatment of hernias where the connective tissue has ruptured or for implantation to reinforce soft tissues where weakness exists in the urological, gynecological and gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support including urethral slings, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, sacral colposuspension and reinforcement in the repair of Peyronie's disease. By providing pubourethral support, the AMS collagen dermal matrix may be used for the treatment of urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

Prescription Use___X___ AND/OR Over-The Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K050445

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: AMS Apogee System with Pre-Connected AMS Collagen Dermal Matrix

Indications For Use: The Apogee System is intended for use in vaginal vault suspension to treat pelvic organ prolapse.

Prescription Use___X___ AND/OR Over-The Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050445

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: AMS Perigee System with Pre-Connected AMS Collagen Dermal Matrix

Indications For Use: The Perigee™ System is intended for the placement of graft material in the anterior vaginal wall via the obturator foramen for the treatment of anterior vaginal wall prolapse.

Prescription Use___X___ AND/OR Over-The Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: AMS BioArc™ SP Sling Kit and BioArc TO Subfascial Hammock with Preconnected AMS Collagen Dermal Matrix

Indications For Use: The BioArc SP Sling Kit and BioArc TO Subfascial Hammock are intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and / or intrinsic sphincter deficiency.

Prescription Use___X___ AND/OR Over-The Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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...(k) Number K050445